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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,825	01/29/2004	Leigh Ward	FAK-101.DCC	5605

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,825	WARD ET AL.	
	Examiner	Art Unit	
	JONATHAN M.L. FOREMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *47-63 and 68-73* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *68-71* is/are allowed.

7)☒ Claim(s) *47-55,58-67,72 and 73* is/are rejected.

8)☒ Claim(s) *56 and 57* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/11 (2)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/10 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 47, 52, 60 and 63 - 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,270 to Williams in view of JP 10000185 A to Kubota et al. and U.S. Patent No. 5,421,344 to Popp.

In regard to claims 47, 52, 60 and 63 – 67, Williams discloses a method and device for determining a presence or absence of tissue oedema (Col. 1, lines 43 - 47) including a current means for applying an alternating current to at least one anatomical region (Col. 2, lines 51 – 53), wherein the alternating current is a single low frequency greater than 0 kHz, but no greater than 30 kHz (Col. 2, lines 5 – 6); a monitoring means to measure bioelectrical impedance of said at least one anatomical region and produce a signal characteristic of bioimpedance for said at least one anatomical region (Col. 2, lines 55 – 56); and an analysis means to process signals from a first and a

second measurement of bioelectrical impedance to obtain a result to thereby provide an indication of a presence or absence of tissue oedema (Col. 2, lines 63 – 67; Col. 7, lines 1 - 20). The first and second measurements are of a same anatomical region separated in time. The current means includes a proximal electrode and a distal electrode in electrical communication with a power source (Col. 6, lines 44 – 51). The analysis means is at least one processing means programmed to perform analysis of data in relation to the first and second measurement of bioelectrical impedance (Col. 7, lines 1 – 20). Williams discloses means for recording bioimpedance (Col. 7, lines 1 – 20). However, Williams fails to disclose determining if the result is outside an expected range for an unaffected population to provide an indication of a presence or absence of tissue oedema. Kubota et al. disclose a method and device for determining a presence or absence of tissue oedema including comparing a measured bioelectrical impedance value with a reference value of a population unaffected by tissue oedema, and determining if the result is outside the expected range to provide an indication of a presence or absence of tissue oedema (See Abstract; Claim 4). The claims would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing a measured bioelectrical impedance value with a value from a population unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema as taught by Kubota et al. with the method and device of Williams for the predictable result of judging whether or not oedema is present in the tissue. However, Kubota et al. in view of Williams fail to disclose the reference value being derived from a population of unaffected subjects. Popp teach that historically reference values derived from a plurality of unaffected subjects are used to compare measured values of individuals to determine the presence or severity of different characteristics (Col. 1, lines 14 -21). The claims would have

been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing measured values of an individual to a reference value of a plurality of unaffected subjects as taught by Popp for the predictable result of diagnosing the presence or severity of an illness or condition.

4. Claims 58, 59, 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,270 to Williams in view of JP 10000185 A to Kubota et al. and U.S. Patent No. 5,421,344 to Popp as applied to claim 47 above, and further in view of U.S. Patent No. 5,505,209 to Reining.

In regard to claims 58, 59, 72 and 73, Williams in view of Kubota et al. and Popp fail to disclose establishing a correction factor from a plurality of subjects unaffected by tissue oedema. Reining discloses a bioelectrical impedance measuring method wherein a correction factor is established from a plurality of subjects in a normal population (See Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Williams in view of Kubota et al. and Popp to include establishing a correction factor from a plurality of subjects unaffected by tissue oedema as taught by Reining in order to minimize error in the measurement (See Abstract).

5. Claims 47 – 55 and 60 – 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,788,643 to Feldman in view of JP 10000185 A to Kubota et al. and U.S. Patent No. 5,421,344 to Popp.

In regard to claims 47 – 55 and 60 – 67, Feldman discloses a method and device for determining a presence or absence of tissue oedema including a current means for applying an alternating current to at least one anatomical region (Col. 2, lines 16 – 17), wherein the alternating

current is a single low frequency greater than 0 kHz, but no greater than 30 kHz (Col. 5, lines 10 – 17); a monitoring means to measure bioelectrical impedance of said at least one anatomical region and produce a signal characteristic of bioimpedance for said at least one anatomical region (Col. 5, lines 33 – 36); and an analysis means to process signals from a first and a second measurement of bioelectrical impedance to obtain a result to thereby provide an indication of a presence or absence of tissue oedema (Col. 6, lines 1 – 26). The first and second measurements are of a same anatomical region separated in time (Col. 6, lines 17 – 26). The first measurement of bioelectrical impedance is of a first anatomical region of the subject and the second measurement of bioelectrical impedance is of a second anatomical region different than the first anatomical region of the same subject. The first anatomical region and the second anatomical region are paired similar anatomical regions and wherein one of the anatomical regions is unaffected by tissue oedema. The first anatomical region and the second anatomical region are dissimilar and wherein one of the anatomical regions is unaffected by tissue oedema. The anatomical regions are limbs or parts of limbs (Col. 3, lines 57 – 60; Col. 4, line 63 – Col. 5, line 9). The single low frequency alternating current is 10kHz (Col. 5, line 14). The current means includes a proximal electrode and a distal electrode in electrical communication with a power source (Col. 4, line 63 – Col. 5, line 9). The analysis means is at least one processing means programmed to perform analysis of data in relation to the first and second measurement of bioelectrical impedance (Col. 6, lines 17 – 26). Feldman discloses means for recording bioimpedance (Col. 6, line 7). Feldman discloses comparing a bioelectrical impedance measurement to a baseline impedance value (Col. 6, lines 1 – 26), but fails to disclose the measurement being compared with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema. Kubota et al. disclose a method and device for determining a presence or absence of tissue oedema

including comparing a measured bioelectrical impedance value with a reference value of a population unaffected by tissue oedema, and determining if the result is outside the expected range to provide an indication of a presence or absence of tissue oedema (See Abstract; Claim 4). The claims would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing a measured bioelectrical impedance value with a value from a population unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema as taught by Kubota et al. with the method and device of Feldman for the predictable result of judging whether or not oedema is present in the tissue. However, Kubota et al. in view of Williams fail to disclose the reference value being derived from a population of unaffected subjects. Popp teach that historically reference values derived from a plurality of unaffected subjects are used to compare measured values of individuals to determine the presence or severity of different characteristics (Col. 1, lines 14 -21). The claims would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing measured values of an individual to a reference value of a plurality of unaffected subjects as taught by Popp for the predictable result of diagnosing the presence or severity of an illness or condition.

Allowable Subject Matter

6. Claims 56 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 68 - 71 are allowed.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M.L. FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736